PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Pitrion

Cream

Active ingredient: miconazole nitrate 2%.
For the list of inactive ingredients, please see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.
Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

The medicine is not intended for children under the age of two, unless instructed by the doctor.
Use this medicine in the correct manner. Consult the pharmacist if you need additional information.
Refer to your doctor if the symptoms get worse, or do not improve after 4 weeks.

1. What is the medicine intended for?

The cream is intended for treatment of skin and nail fungal infections.
Therapeutic Group: antifungal.

2. Before using the medicine

Do not use the medicine if:

Do not use if you are sensitive (allergic) to the active ingredient (miconazole), to any other ingredients from the imidazole group and their derivatives, or to any of the additional ingredients the cream contains (for the list of the inactive ingredients, please see section 6).

Special warnings regarding the use of the medicine:

- Before using for the first time, it is advisable to consult your doctor to avoid unnecessary use.
- Do not use frequently, or for a long period, without consulting your doctor.
- If you are sensitive to any food or medicine, inform the doctor before using the cream.
- In the event of irritation, itching or any sensitivity (including hypersensitivity) to the cream, stop the use immediately.

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking oral anticoagulants for blood thinning, such as warfarin. If you are unsure whether you are using these medicines, please consult with the doctor or pharmacist.

Pregnancy and breastfeeding:
Do not use the medicine without consulting a doctor before starting the treatment if you are pregnant, think you may be pregnant, are planning a pregnancy or are breastfeeding. The doctor will decide if you can use the medicine during pregnancy or breastfeeding.

Use in children: this medicine is not intended for children under the age of two, unless instructed by your doctor.

Driving and use of machinery: This medicine has no effect on driving and/or operation of machinery.

Important information about some of the medicine's ingredients:
Some of the medicine's ingredients may cause an allergy and skin reactions in certain people (for a list of the inactive ingredients, please see section 6).

3. How to use the medicine?

- **Attention!** Not to be swallowed! This medicine is intended for external use only.
- Avoid contact with the eyes.

The standard dosage is usually:

- Apply to the infected area twice daily. Continue the treatment for seven days after all the symptoms have disappeared, in order to prevent their appearance.
- The duration of treatment may vary from 2 to 6 weeks, according to the location and severity of the infection.
- **Do not exceed the recommended dose**
  You should check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
- If there is no improvement in your condition within 4 weeks or if there is a deterioration, refer to the doctor.

How to apply the cream?

- Wash the infected area and dry it well.
- Apply the cream to the infected area and to the surrounding skin.
- Wash your hands thoroughly after applying the cream (unless the fungal infection is on the hands), in order to prevent the spreading of the fungal infection to other areas of the body or to other people.
- Since many skin infections are contagious, make sure that you have a towel and washcloth for your exclusive use to prevent contagion.
- Likewise, frequently change and wash clothes that were in contact with the infected areas, such as socks.

If you accidentally used a higher dosage: excessive use can lead to skin irritation, which usually disappears after discontinuing of the treatment. If somebody accidentally swallowed the cream, refer immediately to a doctor or a hospital emergency room and bring the medicine package along.
If you forgot to take the medicine: If you forgot to use one dose, use the next dose as required. **Do not** use a double dose.

How can you contribute to the success of the treatment?

- Moisture enhances fungal growth; therefore you should keep the infected area dry.
- Wash the infected area before every application of the cream and dry it well with a personal towel.
- If the treatment is on the feet - make sure to wash and dry thoroughly, especially between the toes. Preferable to wear cotton socks. Avoid wearing socks made of wool or synthetic materials. In the appropriate seasons it is recommended to wear sandals without socks.
- Do not bandage the treated area, without the doctor's instructions.
- Do not use or take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
- If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, the use of Pitrion may cause side effects in some users. If the side effects persist or are bothersome or get worse, please consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and refer to the doctor immediately if any of the following side effects appear (see also special warnings in section 2):

Uncommon side effects (appear in 1-10 users out of 1,000):

Skin burning sensation, skin inflammation, local reactions in the area of application (e.g. irritation, burning, heat, itching), change in skin color (including hypopigmentation).

Side effects of unknown frequency (side effects whose frequency has not yet been determined):

- Severe allergic reaction, anaphylactic reaction or angioedema. The symptoms may include, inter alia, swelling of the face, lips, tongue or throat.
- Additional allergic reactions, such as nettle rash (urticaria), skin inflammation upon contact (contact dermatitis), irritated skin, rash, redness, itching.

Side effects and drug interaction in children:

Parents must inform the attending doctor of any side effect, as well as any additional medicine given to the child. See above for detailed side effects and drug interactions.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25^0C.

After the first opening of the tube, the cream may be used for 3 months, but no later than the expiry date imprinted on the package.

6. Additional information

In addition to the active ingredient, the cream also contains the following inactive ingredients:

Stearoyl macrogolglycerides, propylene glycol, isopropyl myristate, cetyl alcohol, polysorbate 80, mixture of parabens (methyl, ethyl, butyl, isobutyl and propyl paraben in 2-phenoxyethanol), sorbitan sesquioleate, carbomer, monoethanolamine, disodium edetate, water.

What does the medicine look like and what does the package contain?

White cream in an aluminum tube.

Manufacturer and Registration holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 067-41-27977

Revised in July 2023 according to MOH's guidelines.

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